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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,175	09/23/2003	Nicole Zitzmann	080618-0304	1693
22428	7590	07/14/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			HORNING, MICHELLE S	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/669,175

Applicant(s)

ZITZMANN ET AL.

Examiner

Michelle Horning

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 42-45, 47, 49-54 and 58-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-45, 47, 49-54, and 58-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Non-Final Office Action is in response to communication filed on 5/22/2006. The finality of the Final Rejection filed on 2/22/2006 has been withdrawn. The current status of the claims is as follows: claims 42-45, 47, 49-54, and 58-66 are under examination and claims 46, 48 and 56-57 have been cancelled.

Of note, this application has been transferred to another patent examiner. Please direct any further correspondence regarding this application to Examiner Michelle Horning.

### ***Claim Rejections***

#### **35 U.S.C. 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

***Claims 42-44, 49-53 and 58-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz and MacKinnon (Neuron) in view of Carrère-Kremer et. al (cited by applicant) and Rokitskaya et. al. (Biochemistry).*** Swartz and MacKinnon teach a method of screening for inhibitors of ion channel function using electrophysiology techniques. Swartz and MacKinnon specifically disclose a method of measuring the changes in membrane permeability induced by ion channel activity in the presence and absence of test compounds (figure 1A and B). Swartz and MacKinnon do not disclose using this method with HCV p7. Carrère-Kremer et. al. disclose that the HCV p7 polypeptide is localized within the membrane, crossing the plasma membrane twice (results) and that the transmembrane domains induce leak when associated with ER membranes (page 3728, paragraph 2 of col. 1). Further, Carrère-Kremer et. al. suggest that HCV p7 may be able to modify membrane permeability (page 3729, paragraph 2 of col. 2) and this polypeptide may play a functional role in the secretory HCV pathway (page 3728, paragraph 1 of col. 2). Black lipid membranes in combination with biotinylated channels are widely used in the arts to study ion channels kinetics, including channel formation and conductance, and Rokitskaya et. al. teach this method (see introduction). Of note, Carrère-Kremer et. al. teach SEQ ID NO:1 (figure 1).

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Swartz and MacKinnon, Carrère-Kremer et. al. and Rokitskaya et. al. in order to measure changes in membrane permeabilities caused by blocking channel activity and/or formation of HCV p7 polypeptides. One would have been motivated to do so, given by the suggestion of Carrère-Kremer et. al., because an inhibitor would

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attenuate the role of HCV p7 in the secretory pathway. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the claims mentioned above are rejected.

***Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz and MacKinnon, Carrère-Kremer et. al. and Rokitskaya et. al. as applied to claims 42-44, 49-53 and 58-66 above, and further in view of Smith JP.*** Smith JP teach that treatment of chronic hepatitis C with amantadine leads to a loss of serum alanine aminotransferase values and HCV RNA. Because amantadine is widely used in the prior art for treatment of HCV as taught by Smith JP, it would have been obvious to one of ordinary skill in the art to use amantadine in the method of screening for p7 inhibitors. One would have been motivated to do so, given by the teachings of Smith JP, to further determine amantadine's role in the therapeutic treatment of HCV.

### **35 U.S.C. 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

***Claims 45, 47 and 60-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*** Claims 45 and 60 read "protein comprises at least one transmembrane domain" yet they are dependent on claims directed to a full-length p7; thus, it appears that these claims are not further limiting. If applicant intends to claim a full-length p7 and an additional

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transmembrane domain, then the usage of "further comprising" is suggested, given this complex is disclosed by the specification. Thus, the claims mentioned above are rejected.


### CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michelle Horning  
Patent Examiner



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